

Application No.: 09/557,796 Attorney Docket No.: 252/123  
Filing Date: April 25, 2000 (037002-0205)  
Response after Final Office Action (mailed July 14, 2003, Paper No. 24) faxed October 14, 2003  
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### Remarks

By this response, claims 99, 135 and 136 have been amended to define Applicants' invention with greater particularity. These amendments add no new matter and are fully supported by the specification as filed. Claims 101, 102, 108, 109, 130, 131 and 133 have been cancelled without prejudice in order to reduce the issues. Applicants respectfully submit that the amendments presented herein place the application in condition for allowance or, at a minimum, reduce the issues for appeal. Accordingly, entry of the amendments is respectfully requested.

Accordingly, claims 99, 100, 103-105, 107, 132 and 134-136 are currently pending. The present status of all claims in the application, and current amendments thereto, are provided in the listing of claims presented herein beginning on page 2.

The rejection of claims 99-104, 107-109 and 131-134 under 35 U.S.C. § 102(b), as allegedly being anticipated by U.S. Patent No. 5,032,514 to Anderson *et al.* (hereinafter referred to as "Anderson"), is respectfully traversed. Applicants' invention, as defined by claim 99 as amended, distinguishes over Anderson by requiring a recombinant cell comprising two distinct recombinant nucleic acid molecules. Specifically, a first recombinant nucleic acid molecule encodes one or more polypeptides that convert a source compound to a target compound; and a second recombinant nucleic acid molecule that comprises a reporter gene and an inducible promoter that responds to the target molecule to provide a detectable signal.

In contrast, as acknowledged by the Examiner (see Office Action, Paper No. 24, at page 4, lines 20-21) Anderson's system uses native enzymes of an endogenous pathway, and does not teach the introduction of two distinct recombinant nucleic acid molecules as contemplated by the present claims.

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Claims 100, 103, 104, 107, 132 and 134, all ultimately depend from amended claim 99; and claims 101, 102, 108, 109, 131 and 133 have been cancelled herein. Thus, Anderson does not teach each and every element of any of the presently pending claims. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection of claims 99-104, 107-109 and 131-134 under 35 U.S.C. § 102(b).

The rejection of claims 99, 102, 104 and 105 under 35 U.S.C. § 102(b), as allegedly being anticipated by Wood and Ingram, *App. Env. Microbiol.* 58:2103-2110, 1992 (hereinafter referred to as "Wood"), is respectfully traversed. Applicants' invention, as defined by claim 99 as amended, distinguishes over Wood by requiring a recombinant cell comprising a recombinant nucleic acid molecule that comprises a reporter gene and an inducible promoter.

Wood does not teach a recombinant nucleic acid molecule of any kind containing an inducible promoter. Claims 102, 104 and 105, all ultimately depend from claim amended claim 99. Thus, Wood does not teach each and every element of any of the presently pending claims. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection of claims 99, 102, 104 and 105 under 35 U.S.C. § 102(b).

The rejection of claims 135 and 136 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite, is respectfully traversed. Applicants respectfully submit that the term is phrase "Yia-operon related polypeptides" is clear to one of skill in the art in light of the teachings of the specification. However, in order to advance prosecution and reduce the issues for appeal, claim 135 has been amended to remove this phrase. Claim 135, as amended, and claim 136 dependent thereon, require a promoter derived from a Yia-operon polypeptide. The specification clearly identifies at least 9 different Yia-operon polypeptides to support the present claims (see, for example, specification at page 18, lines 7-11). Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection of claims 135 and 136 under 35 U.S.C. § 112, second paragraph.

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The rejection of claims 135 and 136 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention, is respectfully traversed. Claim 135, as amended, requires the second recombinant nucleic acid molecule to comprise an inducible promoter that is derived from a Yia-operon polypeptide. Applicants respectfully submit that such promoters, and the Yia-operon polypeptides from which they are derived, are well-known in the art. Applicants' claims are not directed to Yia-operon polypeptides. As such, case law pertaining to claims directed to nucleic acids is not applicable to the present application.

Instead, the present claims merely utilize the promoters of already known genes to create a recombinant nucleic acid molecule that is inducible. One of skill in the art would have no reason to doubt that Applicants were in possession of the claimed recombinant cells, which contain as a component of the working inducible system an inducible promoter derived from a Yia-operon polypeptide. An appropriate comparison might be, for example, the use of an inducible IPTG-inducible promoter (such as the *lac* promoter that is well-known in the art) in cells used to produce a recombinant inducible protein product. Thus, Applicants have provided a more than adequate written description of the claimed recombinant cells to one of skill in the art. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection of claims 135 and 136 under 35 U.S.C. § 112, first paragraph.

The rejection of claims 99-102, 107 and 134-136 under 35 U.S.C. § 102(b), as allegedly being anticipated by Badia *et al.*, *J. Biol. Chem.* 273:8376-8381, 1998 (hereinafter referred to as "Badia"), is respectfully traversed. Applicants' invention, as defined by claim 99 as amended, distinguishes over Badia by requiring a recombinant cell comprising a second recombinant nucleic acid molecule that comprises a reporter gene and an inducible promoter.

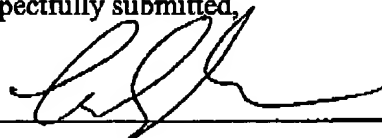
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Badia does not teach a recombinant nucleic acid molecule containing an inducible promoter and a reporter gene. Claims 100, 107, and 134-136, all ultimately depend from amended claim 99; and claims 101 and 102 have been cancelled herein. Thus, Badia does not teach each and every element of any of the presently pending claims. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection of claims 99-102, 107 and 134-136 under 35 U.S.C. § 102(b).

**Conclusion**

In view of the above amendments and remarks, prompt and favorable action on all claims is respectfully requested. In the event any matters remain to be resolved in view of this communication, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved.

Respectfully submitted,



Date: October 14, 2003

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